REMARKS

This Amendment is being filed in response to the Office Action mailed from the U.S. Patent and Trademark Office on November 16, 2004, in which claims 17-28 and 49-82 were rejected. With this Amendment, independent claims 17, 49, 61, 63 and 73 are amended.

The Office Action rejected claims 17-28 and 49-82 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,547,724 to Soble et al. ("the Soble et al. '724 patent") in view of U.S. Patent No. 5,391,144 to Sakurai et al. ("the Sakurai et al. '144 patent"). Also, the Office Action rejected claims 17-28 and 49-82 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over various combinations of Applicants' patents and copending patent applications.

Obviousness Rejection Under 35 U.S.C. 103(a)

The Office Action rejected claims 17-28 and 49-82 under 35 U.S.C. 103(a) as being unpatentable over the Soble et al. '724 patent in view of the Sakurai et al. '144 patent. The Office Action stated on pages 9 and 10:

> **Soble et al. '724 do not expressly teach the probe supporting transverse ultrasonic vibration along at least a portion of the axial length of the probe** and wherein the vibration of the probe provides a plurality of anti-nodes along at least a portion of the axial length.
>
> In the same field of endeavor, Sakurai et al. '144 teach the probe supporting transverse ultrasonic vibration along at least a portion of the axial length of the probe and wherein the vibration of the probe provides a plurality of anti-nodes along at least a portion of the axial length (in Figure 13, see how the horn (element 63) transmits the vibrations to the ultrasonic probes (elements 61 or 62) with the transverse oscillation of the probe indicated in Figures 40 and 41 with indications of anti-node or loops wherein there is maximum oscillation along the length of the probes).
>
> It would have been obvious to one skilled in the art at the time that the invention was made to have modified Soble et al. '724 in view of Sakurai et al.' 144 and incorporated the specific teachings of Sakurai et al. '144 by using the specific probe as the probe of choice in lithotripsy by utilizing transverse vibration as this is such an ultrasonic device (see in col. 1, lines 12-16, describing use of device for breaking stones).

"Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or

motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." M.P.E.P. 2143.01. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab,* 217 F.3d 1365, 1370, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000). See also *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Lee*, 277 F.3d 1338, 1342-44, 61 U.S.P.Q.2d 1430, 1433-44 (Fed. Cir. 2002); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); M.P.E.P. 2143.01.

With this Amendment, Applicants have amended independent claims 17, 49, 61, 63 and 73 to claim an **ultrasonic probe supports a transverse ultrasonic vibration along at least a portion of a longitudinal axis of the ultrasonic probe.** Support for these Amendments is found throughout Applicants' Specification as filed. No new matter is added.

Regarding the primary reference, the Soble et al. '724 patent, Applicants agree with the Office Action's statement on p. 9 that " Soble et al. '724 do not teach the probe supporting transverse ultrasonic vibration."

The additional cited reference of the Sakurai et al. '144 patent does do not cure or offer a suggestion on how to overcome the deficiencies of the Soble et al. '724 patent. Applicants respectfully disagree with the Office Action's statement on p. 9 that "Sakurai et al. '144 teach the probe supporting a transverse ultrasonic vibration." The Sakurai et al. '144 patent does not disclose transverse ultrasonic vibration. In fact, the Sakurai et al. '144 patent does NOT contain any form of the word "transverse." As shown in the detailed analysis below, the Sakurai et al. '144 patent discloses longitudinal ultrasonic vibration, and does NOT disclose transverse ultrasonic vibration.

Examination of the Sakurai et al. '144 patent shows the Sakurai et al. '144 patent discloses longitudinal ultrasonic vibration and not transverse ultrasonic vibration. Differentiation between the Sakurai et al. longitudinal vibration and the Applicants' claimed transverse vibration is evidenced by well known wavelength and stress equations, with further confirmation from the specification of the Sakurai et al. '144 patent.

Sakurai et al. Discloses Longitudinal Vibration – Wavelength Equation Confirmation

Sakurai et al. '144 patent discloses an ultrasonic treatment apparatus that uses longitudinal vibration. Sakurai et al. discloses:

> The ultrasonic oscillator 2 can vibrate in various modes which are represented in the graph, i.e., the lower half of FIG. 40. As may be understood from the graph, the oscillator 2 has indefinite number of vibration modes. **Among these vibration modes are: the fundamental mode; the second harmonic mode in which ultrasonic waves have half the length of those in the fundamental mode; the third harmonic mode in which ultrasonic waves have a third of the length of those in the fundamental mode; and the fourth harmonic mode in which ultrasonic waves have a quarter of the length of those in the fundamental mode.** (Sakurai et al. '144 patent; Col. 23, Line 64 - Col. 24, Line 7)(emphasis added).

The above statement in Sakurai et al. conforms with the equation for the wavelength of **longitudinal vibration** waves produced in a rod:[1]

$$\lambda_n = \frac{2\pi c}{\omega_n}$$ where c is the speed of sound and ω_n is the angular frequency

Substituting the expression for the angular frequency ω_n in terms of the linear frequency, ν_n,

$$\omega_n = 2\pi\nu_n$$

gives

$$\lambda_n = \frac{c}{\nu_n}$$

and finally substituting the expression for normal mode frequencies,

$$\nu_n = \frac{nc}{2L}$$

yields

$$\lambda_n = \frac{2L}{n}$$ where L is the length of the rod.

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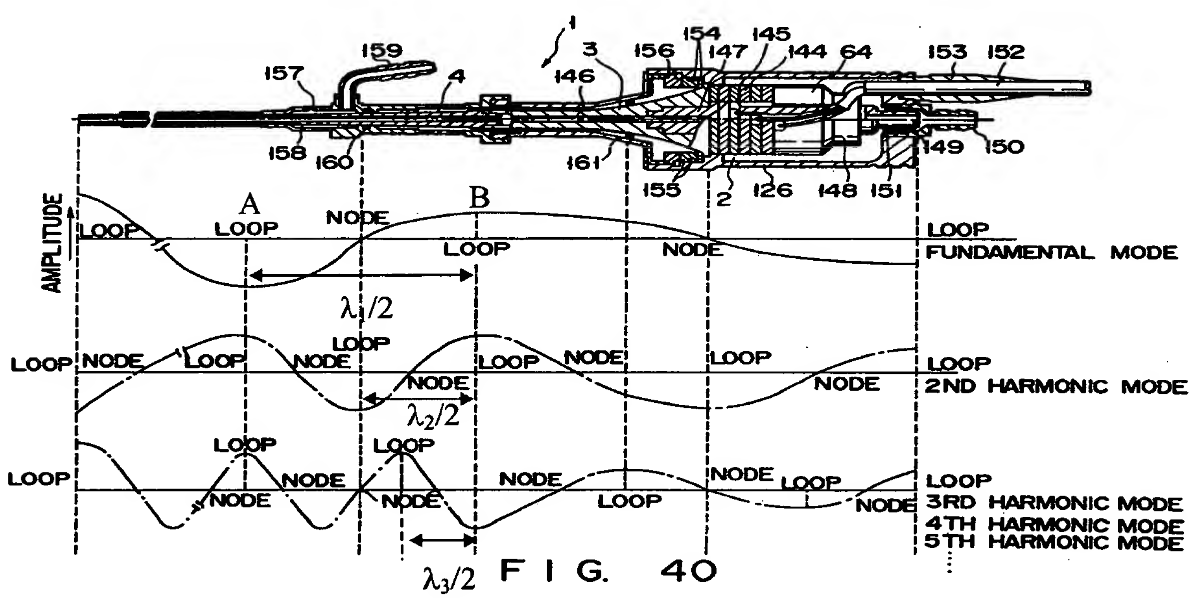
[1] Morse, P.M. and Ingard, K.U., *Theoretical Acoustics*, Princeton University Press, Princeton, NJ, pp. 116-120, 1968 (see attached Exhibit A).

Using this equation for **longitudinal vibration** waves, the fundamental harmonic wavelength is λ_1=2L, the second harmonic wavelength is λ_2=L and the third harmonic wavelength is λ_3=2L/3. Now the ratios of the second harmonic mode to the fundamental mode and the third harmonic mode to the fundamental mode can be calculated as follows:

$\boldsymbol{\lambda_2/\lambda_1 = L/2L = 0.50}$ (Ratio of Second Harmonic Mode to Fundamental Harmonic Mode for a **Longitudinal Vibration** wave)

$\boldsymbol{\lambda_3/\lambda_1 = (2L/3)/2L = 0.33}$ (Ratio of Third Harmonic Mode to Fundamental Harmonic Mode for a **Longitudinal Vibration** wave)

FIG. 40 of Sakurai et al. is reproduced below with annotations A, B, $\lambda_1/2$, $\lambda_2/2$ and $\lambda_3/2$.



F I G. 40

FIG. 40 of Sakurai et al. '144 patent shows plots of amplitude of axial displacement of a longitudinal vibration wave versus position for a longitudinal vibration wave traveling along the device. For a given length L, for example between points A and B, along the transmission member, Sakurai et al. follows the equation for the wavelength of longitudinal vibration waves discussed above. In viewing FIG. 40 of Sakurai et al. between points A and B, λ_1=2L, λ_2=L and λ_3=2L/3. Thus, the ratios for the longitudinal vibration waves λ_2/λ_1 = 0.5 and λ_3/λ_1 = 0.33 hold true for Sakurai et al. which discloses longitudinal vibration modes. Further, FIG. 40 lists the fundamental mode, 2nd harmonic mode and 3rd harmonic mode. The fundamental, 2nd and 3rd

modes are harmonically related which means the wavelengths are integer multiples of each other, further evidence that Sakurai et al. discloses longitudinal vibration.

The plot of the amplitude of axial displacement of a longitudinal vibration wave versus position for a longitudinal vibration wave traveling along the device in FIG. 40 of Sakurai et al. '144 patent showing the loops and nodes of the longitudinal vibration motion of Sakurai et al. DOES NOT depict the device physically moving up and down. This plot is an abstract representation of the maximum deviation from equilibrium of a point at the given position along the longitudinal axis of the device. The plot merely shows an amplitude of axial displacement of a longitudinal vibration versus position for a longitudinal vibration traveling along the device to the tip.

In FIGS. 40-42 of the Sakurai et al. '144 patent, the progression of the wavelengths from fundamental mode to 2nd harmonic mode to 3rd harmonic mode shows the integer multiple relationship between the wavelengths described in the preceding analysis, and not the anharmonic relationship between the transverse vibration modes which will be discussed below.

Transverse Vibration Wavelength Equations

The equation for transverse vibration wavelength can be obtained by examining the solution for the mode shapes of a transverse wave:[2]

$$Y = a[\cosh(2\pi\mu\ x) - \cos(2\pi\mu\ x)] + b[\sinh(2\pi\mu\ x) - \sin(2\pi\mu\ x)]$$

where Y is the amplitude of the wave at position x on the rod, a and b are constants depending upon the specific nature of the problem and $2\pi\mu$ is the wavenumber, k, of the transverse vibration wave. Using the relationship between the wavelength and the wavenumber

$$k = 2\pi\mu = \frac{2\pi}{\lambda}$$

gives

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[2] Morse, P.M. and Ingard, K.U., *Theoretical Acoustics*, Princeton University Press, Princeton, NJ, pp. 181-182, 1968 (see attached Exhibit A).

$$\lambda = \frac{1}{\mu}$$

Substituting the expression for $\mu_n{}^2$ gives the expression for the wavelength of the n^{th} transverse mode:

$$\lambda_n = \frac{2L}{\beta_n} \qquad \text{with } \beta_n = \begin{cases} 0.597 & n = 1 \\ 1.494 & n = 2 \\ n - \frac{1}{2} & n > 2 \end{cases}$$

where L is the length of the rod.

Using this equation for **transverse vibration** waves, the fundamental mode wavelength is λ_1=3.35L, the second mode wavelength is λ_2=1.34L and the third mode wavelength is λ_3=0.8L. Now the ratios of the second mode to the fundamental mode and the third mode to the fundamental mode can be calculated as follows:

λ_2/λ_1 = 1.34L/3.35L = 0.40 (Ratio of Second Mode to Fundamental Mode for a **Transverse Vibration** Wave)

λ_3/λ_1 = 0.8L/3.35L = 0.24 (Ratio of Third Mode to Fundamental Mode for a **Transverse Vibration** Wave)

Comparing the ratios for longitudinal vibration and transverse vibration waves of the second mode and the third mode to the fundamental mode shows the inequality of the ratios for the varying waves. Therefore, further examination of the inequality of the ratios for the longitudinal vibration waves and the transverse vibration waves clearly shows that the Sakurai et al. discloses a longitudinal vibration:

(Longitudinal Vibration Waves) (Sakurai et al. '144 Patent)		**(Transverse Vibration Waves)**
λ_2/λ_1 = 0.50	$\neq$	**λ_2/λ_1 = 0.40**
λ_3/λ_1 = 0.33	$\neq$	**λ_3/λ_1 = 0.24**

As the above analysis shows, examination of equations for longitudinal vibration waves, the Sakurai et al. '144 specification and FIGS. 40-42 all confirm that Sakurai et al. discloses longitudinal vibration.

Sakurai et al. Discloses Longitudinal Vibration – Stress Equation Confirmation

Further evidencing that Sakurai et al. discloses longitudinal vibration is the specification of the Sakurai et al. '144 patent and well known stress equations. The Sakurai et al. '144 patent specification discusses a statement applicable to longitudinal vibration waves, but not applicable to transverse vibration waves:

> As is evident from FIG. 42, the junction between the horn 3 and the member 4, the first junction 171, and the second junction 177 are located at the loops of the ultrasonic vibration of the vibration-transmitting member 4. As is generally known in the art, less stress is applied to those portion of any member which are located at the loops of ultrasonic vibration, than to those portions which are located at the nodes of the vibration. Hence, a relatively small stress acts on the junction between the horn 3 and the member 4, the first junction 171, and the second junction 177--all being mechanically weak. (Sakurai et al. '144; Col. 25, Line 63 - Col. 26, Line 5).

The above statement is only true for longitudinal vibration waves, and not transverse vibration waves. Therefore, for the longitudinal vibration disclosed in Sakurai et al., there is little stress at the members located at the loops.

The well known equation for stress in a rod deformed by **transverse vibration** is:[3]

$$\sigma = \frac{Mc}{I} = Ec\frac{d^2v}{dx^2}$$

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[3] Craig, R.R. Jr., *Mechanics of Materials*, John Wiley and Sons, New York, NY, p. 268, 1996 (see attached Exhibit B).

where σ is the stress, M is the bending moment, c is the thickness of the rod, I is the moment of inertia of the rod, E is the Young's modulus of the rod, v is the transverse displacement of the rod, and x is the coordinate along the axis of the rod.

For a rod undergoing transverse vibration in a normal mode, the spatial distribution of the transverse displacement amplitude can be approximated by a sinusoidal wave pattern as follows:

$$v = A\sin(kx)$$

substituting this into the stress equation yields:

$$\sigma = -Eck^2 A\sin(kx)$$

Therefore, for transverse vibration, it is clear that the maximum values for the stress are coincident with the points of maximum displacement ($kx = ((2n+1)\pi)/2$), which are defined as the loops and the minimum values for the stress are coincident with the points of minimum displacement, which are defined as the nodes. Conversely, the longitudinal vibration disclosed in Sakurai et al. incurs maximum stress at the nodes. Therefore, the stress equations confirm the Sakurai et al. '144 patent discloses longitudinal vibration, not transverse vibration.

Sakurai et al. Discloses Longitudinal Vibration And Energy Transfer Occurs At Tip

The Sakurai et al. '144 patent discloses longitudinal vibration that can only efficiently deliver energy to a surrounding medium at its tip. The longitudinal vibration operates by pushing material in an oscillatory fashion along the longitudinal axis of the rod only. This means that material along the side of a longitudinally oscillating rod is affected far less than material at the tip. Along the side, the rod is moving parallel to the surface of the adjacent material and little mechanical energy other than frictional heat is transferred from the rod into the surrounding material. At the tip, the rod is moving perpendicular to the surface of the adjacent material and much more mechanical energy can be imparted. Regarding FIG. 40 of the Sakurai et al. '144 patent (reproduced above), the only effective loop for transferring mechanical energy from a longitudinal vibration would be the one at the tip. Any other loop along the device is rendered ineffective because it can only vibrate parallel to the surface of a material with which it is in contact.

Sakurai et al. '144 discloses an ultrasonic treatment apparatus using longitudinal vibration that emulsifies tissue at the tip of the Sakurai et al. device. Sakurai et al. discloses:

> The **tips** of probes of different types, which can be attached to the hand piece, must be vibrated at different amplitudes to emulsify different types of tissues within body cavities, each type with the highest possible efficiency. (Sakurai et al. '144; Col. 12, Lines 24-28) (Emphasis added)
>
> If the **tip** of the probe 61 is in contact with a living tissue within a body cavity, it **emulsifies the tissue**." (Sakurai et al. '144; Col. 13, Lines 16-17)
>
> The **tip** of the member 4 is vibrated, and can therefore **cut or emulsify an affected tissue** or can break stones in a body cavity." (Sakurai et al. '144; Col. 23, Lines 61-63) (Emphasis Added)

Sakurai et al. discloses a device that uses longitudinal vibration. Sakurai et al. does <u>NOT</u> disclose or suggest an **ultrasonic probe supports a transverse ultrasonic vibration along at least a portion of a longitudinal axis of the ultrasonic probe**. The Sakurai et al. '144 patent does not cure or offer a suggestion on how to overcome the deficiencies of the Soble et al. '724 patent. Applicants respectfully request withdrawal of the obvious rejections and reconsideration and allowance of pending claims 17-28 and 49-82.

Double Patenting Rejections

The Office Action rejected claims 17-28 and 49-82 under the judicially created doctrine of obviousness-type double patenting as being unpatentable based on claims of five issued patents and seven pending patent applications: U.S. Patent No. 6,524,251; U.S. Patent No. 6,660,013; U.S. Patent No. 6,652,547; U.S. Patent No. 6,679,873; U.S. Patent No. 6,695,781; copending Application No. 10/071,953; copending Application No. 10/268,487; copending Application No. 10/268,843; copending Application No. 10/371,781; copending Application No. 10/373,134; copending Application No. 10/396,914 and copending Application No. 10/462,182 (please note that Application No. 10/462,182 is U.S. Patent No. 6,679,873 listed above).

Applicants believe the present application claims separate and distinct subject matter than the five patents and seven pending patent applications. Thus, Applicants respectfully request withdrawal of all double patenting rejections because the present application claims subject

matter that is patentably distinct from the claimed subject matter in the five patents and seven applications.

<u>The Present Application Claims Subject Matter That Is Patentably Distinct</u>

The MPEP definition of Obviousness-Type Double Patenting states:

> Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is **not patentably distinct** from the subject matter claimed in a commonly owned patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).

MPEP 804(II)(B)(1) (emphasis in original).

Applicants respectfully state that the present application claims subject matter that is patentably distinct from the claimed subject matter in the five patents and seven patent applications. Thus, the present application is not claiming common subject matter with the five patents and seven patent applications.

The present application is entitled "Method and Apparatus for Ultrasonic Medical Treatment, in Particular, for Debulking the Prostrate." The present application relates to an apparatus and a method for using an ultrasonic medical device operating in a transverse mode <u>to debulk the prostrate</u>.

Independent claims 17, 49, 61 and 73 of the present application all include the following limitation:

> an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe, wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe

The aspiration channel recessed along the length of an outer surface of the ultrasonic probe assists in debulking the prostate. The claims in the five patents and seven applications do <u>not</u> contain such a limitation. The limitation is <u>not</u> an obvious variation of the patented claims. Thus, the present application claims subject matter that <u>is patentably distinct</u> from the claimed subject matter in the five patents and seven applications. Thus, Applicants respectfully request

withdrawal of all double patenting rejections and reconsideration and allowance of claims 17-28 and 49-82.

Regarding Application No. 10/396,914, the Office Action's reference to the Soble et al. '724 patent is misplaced. Soble does not make obvious the aspiration channel recessed along the length of an outer surface of the ultrasonic probe. Tthe Soble et al. '724 patent does not teach an aspiration channel recessed along the length of an outer surface of the ultrasonic probe as claimed in Applicants' claimed invention. The Office Action on pages 6-7 asserts that Soble teaches an aspiration channel recessed along the length of an outer surface of the ultrasonic probe as follows:

> In the same field of endeavor, Sobel et al. '724 teach at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe, wherein aspiration occurs through the at least one aspiration channel along the length of the probe (see col. 6, lines 9-27).

Applicants respectfully disagree with the Office Action's above characterization of Soble et al. '724 patent. Soble discloses a flexible sleeve for placing over a flexible endoscope with the sleeve containing lumens therein. As shown in FIGS. 3A, 3B and 3C the Soble lumens are located inside the sleeve 10. Further, the Office Action's reference to col. 6, lines 9-27 of Soble et al. '724 patent does not teach an aspiration channel recessed along the length of an outer surface of the ultrasonic probe as shown below:

> In another aspect of the invention, the **sleeve may contain multiple lumens defined by partition structures.** Apertures connected to these lumens may be part of the sleeve's distal opening, proximal opening, or its radial surface. As shown in **FIG. 3A, the sleeve 10 may contain, for example, three lumens defined by partition structure 6.** Lumen 1 is sized for insertion of the medical instrument (not shown). **One of the lumens can be used as an irrigation or ventilation channel** 3 connected to a source of pressurized fluid. Lumen 2 illustrates another working channel.
>
> The lumens can be substantially co-axial, as shown in FIG. 3B. All or one of the outer lumens may be used as the irrigation/ventilation channel 3 connected through an aperture (not shown) to a source of irrigation or ventilation. That aperture may be the port 20. The channel 3 can run along the length of the sleeve 10, which prevents the collapse of the cavity under treatment during suction by providing enough fluid flow to the cavity to counteract the vacuum caused by suction.

(Soble et al. '724 patent; col. 6, lines 9-27) (emphasis added). As the above passages show, Soble et al. '724 patent teaches lumens located inside a sleeve that can be used as an irrigation or ventilation channel.

Soble et al. '724 patent does not teach an aspiration channel recessed along the length of an outer surface of the ultrasonic probe. Thus, it would not have been obvious to one skilled in the art to modify the claims of the patent application based on Soble et al. '724 patent to claim an aspiration channel recessed along the length of an outer surface of the ultrasonic probe.

Thus, the present application claims subject matter that is patentably distinct from the claimed subject matter in the five patents and seven applications. Thus, Applicants respectfully request withdrawal of all double patenting rejections and reconsideration and allowance of claims 17-28 and 49-82.

Conclusion

In summary, the cited prior references, alone or in combination, do not anticipate, suggest, or make obvious Applicants' claimed invention in pending claims 17-28 and 49-82 and the rejections in the Office Action should accordingly be withdrawn. Reconsideration and allowance of pending claims 17-28 and 49-82 is respectfully requested.

Applicants have made an earnest effort to respond to all issues raised in the Office Action of November 16, 2004, and to place all claims presented in condition for allowance. No amendment made was for the purpose of narrowing the scope of any claim, unless Applicants have argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Respectfully submitted,

Date: March 16, 2005

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